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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/058,589	04/10/1998	IAN KIMBER	138.41.US01	7637

27194 7590 03/07/2002

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/058,589

Applicant(s)

KIMBER ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-18 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10, 12-14 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted December 5, 2001 is acknowledged.

Claims Rejection 35 U.S.C. – 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-10,12-14 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Britigan (Advances in Experimental Medicine and Biology, Vol. 357, page 143-156, 1994), Greff (CAPlus Abstract, AN 1988:226674) and De Lacharriere et al. (US Patent 5,658,581) for essentially the same reasons set forth in the prior office action.

2. Claims 5-10,12-14 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Nuijens et al (of record) and Enk et al. (Proc. Natl. Acad. Sci. USA, Vol 89, pp 1398-1402, provided in IDS of August, 6, 1998), Database WPI AN 95-340208 (IDS October 2, 1998) and Penco et al. (of record) for essentially the same reasons set forth in the prior office action.

3. Regarding the newly added limitation, 'said amount being sufficient to reduce inflammation-induced Langerhans cell migration or accumulation of dendritic cells in lymph

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nodes,' note the ultimate utility of the method is for treating inflammatory disorder. To optimizing an effective amounts of a known therapeutical agent for treating such disorder is considered within the skill of artisan. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates, i.e., reduce Langerhans cell migration, or reduce the accumulation of dendritic cells. Applicants' attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." The ultimate utility for lactoferrin, i.e., anti-inflammation, is known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims, including the newly added claim 20, are properly rejected under 35 U.S.C. 103.

Applicants' amendments and remarks submitted December 5, 2001 have been fully considered. The remarks regarding the rejection over *Conneely et al.* are persuasive. The remarks regarding the other rejection are not persuasive for reasons discussed below.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding the remarks that *Teng et al.* does not provide an enablement for treating lactoferrin-deficient disorder because *Teng* fails to teach how to determine or ascertain lactoferrin deficiency. Note whether *Teng* enabling the full scope for treating lactoferrin

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deficiency is note the issue here. The fact is that Teng teaches the usefulness of lactoferrin for treating dermal inflammatory disorder. What exactly the mechanism for treating the inflammatory disorder by lactoferrin is out the scope of the issue discussed herein.

Regarding the remarks that Britigan et al has not shown the usefulness of lactoferrin in vivo, note other references have shown the usefulness in vivo.

Regarding the remarks of De Lacharriere, note De Lacharriere has used lactoferrin for treating allergen (ingredients of cosmetic or pharmaceuticals)-induced inflammatory. Applicants' attention is directed to the abstract and the claims.

Regarding the remarks that Greff has not expressly teaches for allergen-induced inflammatory, note Greff teaches broadly the usefulness of lactoferrin for treating skin inflammatory disorders. It would have been reasonably expected lactoferrin would be useful for treating skin inflammatory disorders including those induced by allergen.

Applicants asserted that the rejection over Teng et al. in view of Nuijens et al, Enk et al., Database WPI AN 95-340208 and Penco et al. is improper because of the extremely vague and general disclosure of the cited references. The examiner disagrees. The rejection is proper as discussed in the prior office action and the discussion set forth in item 3 of this office action. Particularly, Teng et al. teaches the usefulness of lactoferrin for treating dermal inflammatory disease, Teng et al. does not expressly teaches the treatment of allergen-induced inflammatory disorder. However, the secondary references teaches that lactoferrin is known to be an antagonist of IL-1 or TNF alpha, and IL-1 and TNF alpha are known to be responsible for promoting inflammatory activity, including allergen-induced inflammatory activity. Therefore, It would have been reasonably expected that lactoferrin would be useful for treating allergen-induced

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inflammatory activity as well.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang
AU 1617
January 3, 2001

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

